UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte ASON C. H. SHIH

Appeal No. 2006-0650
Application No. 10/007,613

ON BRIEF

Before MILLS, GRIMES, and LEBOVITZ, Administrative Patent Judges.

LEBOVITZ, Administrative Patent Judge.

DECISION ON APPEAL

This appeal involves claims to systems for disinfecting and decontaminating medical devices and instruments. The examiner has rejected the claims as obvious over prior art. We have jurisdiction under 35 U.S.C. § 134. We affirm.

Background

The invention relates to prion decontamination. Prions are an infectious pathogen comprised of protein. They cause transmissible spongiform encephalopathies, such as "mad cow disease" and Creutzfeldt-Jakob disease. The application describes "a disinfection method for cleansing prion-contaminated" medical devices, kitchen utensils, and other articles which are susceptible to prion

contamination. Specification, page 4. According to the application, raising the temperature (e.g., from about 35°C to about 150°C) of instruments contaminated with prions causes the prions to become susceptible to enzymatic degradation. Id., pages 4-5. After heating the instruments to this temperature, they are contacted with an enzyme at a second temperature to digest the contaminating prions. The process can also be carried out at single temperature, when thermostable enzymes are utilized. Id., page 11.

Discussion

1. Claim construction

Claims 39-51, 53-56, 63, 71, 73, 74, 80, and 82 are on appeal. Claims 1-38, 68-69, and 75-79 are also pending, but have been withdrawn from consideration by the examiner. The claims stand or fall together. See Brief, page 8.

We will consider claims 56 and 82 as representative of the claims subject to each rejection. Claim 56 reads as follows:

> A system comprising:
> (a) one or more articles susceptible to contamination by infectious prion protein;
> (b) means for heating said one or more articles;
> (c) a proteolytic enzyme selected from the group consisting of keratinases and subtilisins; and
> (d) means for exposing said articles to said proteolytic enzyme;
> wherein said one or more articles are characterized by an elevated temperature of from about 40°C to about 60°C and exposure to said proteolytic enzyme.

Claim 82 differs from claim 56 in reciting a specific type of keratinase. In both claims 56 and 82, a "wherein" clause is recited in which the articles are "characterized by" a single temperature range and exposure to a proteolytic enzyme. The "wherein clause" was not literally recited in the application when it was originally filed. However,

the words of a claim "are generally given their ordinary and customary meaning." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582, 39 USPQ2d 1573, 1576 (Fed. Cir. 1996). The "ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." Phillips v. AWH Corp., 415 F.3d 1303, 1313, 75 USPQ2d 1321, 1326 (Fed. Cir. 2005). "[A] person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." Phillips, 415 F.3d at 1313, 75 USPQ2d at 1326. "In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words ... In such circumstances, general purpose dictionaries may be helpful." Phillips, 415 F.3d at 1314, 75 USPQ2d at 1327.

The ordinary and customary usage of the words in the "wherein clause" leads us to its proper construction. We refer to a dictionary for the meaning of "characterized by," since the latter is not defined in the specification. The ordinary meaning of the term "characterize" is "to describe the character or quality of." Webster's New Collegiate Dictionary, 1976. Thus, the recited condition of "from about 40°C to about 60°C" describes the character of the article and the system in which it is placed. Accordingly, we can construe the phrase in these claims to unambiguously mean that the system, and article contained in it, are brought to a temperature within the recited range. This

construction is consistent with the ordinary and customary usage of the words and the specification embodiments.

The article must also be "exposed" to the proteolytic enzyme. We construe this to mean, in accordance with the application, that the article is in contact with the enzyme so degradation of the prior protein can be accomplished. Specification, pages 13-14.

The other term to construe in the claim is "system." This term is not disclosed in the specification or original claims, but made its first appearance in the amendment filed 9/23/2003. Without specific guidance from the specification, we turn to the dictionary definition to elucidate its ordinary and customary meaning. According to Webster's New Collegiate Dictionary (1976), a system is "a regularly interacting or interdependent group of items forming a unified whole." Applying this definition to the claims, the recited elements (a) through (d) are construed to be the "items" which form the "whole," i.e., the system. Although no purpose is recited for the system, the specification indicates it is for "disinfecting and sterilizing medical devices and like articles." Specification, page 2. The elements, i.e., the heating means, exposing means, and proteolytic enzyme, thus interact in the system to perform the disinfection/sterilization purpose.

No specific structures are described in the application, either for the system as a whole or for the several "means for" that are recited in the claim. For instance, the claim states that the articles are characterized by being heated to a certain temperature range and exposed to an enzyme, but it does not require that the heating and contacting be done at the same time or in the same "means for."

The claims also refer to an article "susceptible to contamination by infectious prion protein." The ordinary meaning of the term "susceptible" is "capable of submitting to an action, process, or operation." Webster's New Collegiate Dictionary, 1976. This does not describe a physical limitation to the claim, only a potential act ("contamination") that may occur. Thus, we do not construe the claim to require the presence of prion protein.

2. Obviousness

Claims 39-51, 53-56, 63, 71 and 73 stand rejected under 35 U.S.C. § 103 as obvious over Huth[1]. It is noted that additional references were relied upon in the Answer. Page 3, § 8; page 4. Although we considered these references, we found Huth to be sufficient to sustain the examiner's rejection of claim 56.

Huth is a disclosure of compositions and methods for cleaning and decontaminating medical devices. Huth, Column 10, lines 31-65. It describes prior art processes for cleaning and disinfecting instruments, e.g., utilizing enzyme solutions at particular temperatures (Id., column 9, lines 19-30) and enzyme treatment followed by disinfection (Id., column 12, lines 15-20). The patent describes its own method that employs an enzyme solution with an oxidant (Id., column 10, lines 43-50) to clean and decontaminate devices. The process can be carried out with different enzymes, including thermostable enzymes (Id., column 14, lines 50-column 15, line 12) and at various temperatures (Id., column 28, lines 14-48).

The examiner bears the initial burden of showing unpatentability. See, e.g.,

[1] Huth et al. (Huth), U.S. Pat. No. 6,448,062, issued Sep. 10, 2002.

In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir .1993). A prima facie case of obviousness requires evidence that the prior art disclosed or suggested all of the elements of the claimed invention, and that those skilled in the art would have been motivated to combine those elements with a reasonable expectation of success. See In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970); In re Vaeck, 947 F.2d 488, 493, 20 USPQ2d 1438, 1443 (Fed. Cir .1991).

Most inventions arise from a combination of old elements that are found in the prior art. "However, mere identification in the prior art of each element is insufficient to defeat the patentability of the combined claimed subject matter. . . . Rather, to establish a prima facie case of obviousness based on a combination of elements disclosed in the prior art, the Board must articulate the basis on which it concludes that it would have been obvious to make the claimed invention ... In practice, this requires that the Board 'explain the reasons one of ordinary skill in the art would have been motivated to'" to combine the elements of the prior art. In re Kahn, 441 F.3d 977, 987, 78 USPQ 1329, 1335 (Fed. Cir. 2006).

In setting forth the motivation to have combined the references, the examiner apparently read the claims to require prion decontamination to be achieved, and therefore found it necessary to identify prior art (e.g., WHO[2]) expressly disclosing prions. However, the claims are not so limited. There is no verbiage in them that restricts or requires the system to act on prions. The fact that the articles recited in certain claims are recited to be "susceptible to contamination by infectious prion protein"

[2] "WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies: Report of a WHO Consultation," World Health Organization, (1999).

does not impart the necessary function that the claimed system be designed to eliminate them.

Having construed the claim to not require prion decontamination, any motivation to have combined the elements is adequate to establish obviousness under § 103. In In re Dillon, 919 F.2d 688, 693, 16 USPQ2d 1897, 1901 (Fed. Cir. 1990), the court held "it is not necessary in order to establish a prima facie case of obviousness . . . that there be a suggestion or expectation from the prior art that the claimed [invention] will have the same or a similar utility as one newly discovered by applicant."

The key elements recited in claim 56 include: (b) means for heating articles; (c) a proteolytic enzyme which is a keratinase; and (d) means for exposing articles to enzyme. (Keratinase was elected in response to a restriction requirement.)

The claimed system, as we have construed it, is not restricted to a single apparatus, but can comprise a set of interrelated elements having no particular configuration. Huth gives an example of a system for disinfecting medical devices having elements (b)-(d). Huth, column 27, line 66-column 28. The system ("Steris® System 1™") is described in which a solution containing a proteolytic enzyme (element (c) in claim 56) is delivered to the device for "approximately a 12 min period at between about 43-48°C." Id., column 28, lines 29-43. The delivery (Id., column 28, lines 35-36) and the 12 minute disinfection step at about 43-48°C clearly reflect the existence of the heating means (b) and exposing means (d) of claim 56. The temperature range falls within the claimed range of "from about 40°C to about 60°C."

The use of subtilisin-A is described in the Huth example. Id., column 28, line 24. However, Huth describes the use of keratinases in other sections of the patent (column

15, line 15) for the cleaning and decontamination process. It would have been obvious to have utilized a keratinase, rather than the subtilisin, since Huth teaches these as suitable proteolytic enzymes for the disinfection of medical devices. Id., column 15, lines 13-15. Appellant did not provide any arguments to the contrary.

In another example, Huth describes a pericylinder carrier ("article") which was submerged in a test tube containing a protease ("(d) means for exposing said articles to said proteolytic enzyme") which had been placed in a water bath ("(b) means for heating") to be equilibrated to a specific temperature. Id., Column 31, lines 5-10. At other locations in the patent, Huth teaches enzyme reactions being carried out at, e.g., 40°C (Id., column 32, lines 65-66) and with enzymes active at temperatures of about 50°C (Id., column 15, lines 6-12). As mentioned above, Huth also discloses the proteolytic enzyme to be a keratinase (column 15, line 15). For the same reasons as above, these elements also clearly render obvious the limitations (b)-(d) set forth in claim 56, including the temperature range recited in the "wherein clause."

Appellant argued that the references cited in the rejection do not lead to "the proteolytic enzyme and the exposing means for simultaneous heating and enzyme exposure to allow the articles to be at an elevated temperature in a range of from about 50°C to about 65°C during exposure to a proteolytic enzyme." Brief, page 10, lines 4-7.

This particular range is not recited in claim 56, which we have chosen as a representative claim. Nonetheless, we find Appellant's argument flawed. Huth describe a prior art patent in which cleaning and disinfection of medical instruments was accomplished at 55°C to 65°C using a solution that contained a proteolytic enzyme. Huth, column 9, lines 19-30. Huth also provides examples of proteolytic enzymes which

are "stable and active at temperatures >50°C, or even >100°C." Id., column 15, lines 6-12. A water bath to bring enzyme solutions to a desired temperature is also described in Huth. Id., column 31, lines 5-10. Clearly, Huth describes a system that allows for heating and enzyme exposure at the claimed temperatures, i.e., a test tube in a water bath. See also Id., column 27, line 66-column 48. The system is not restricted to "simultaneous heating and enzyme exposure," as stated by Appellant. There is no limitation in the claims that requires the heating to be accomplished at the same time the enzyme exposure is carried out.

Appellant also states there is "no teaching in Huth of utility for the disclosed enzymes in decontamination of articles infected by prion protein, and a fortiori, no disclosure of utilizing specific temperatures for prion protein decontamination." Rely Brief, Page 7, lines 3-5. However, as we have already pointed out, the claims contain no limitation, express or inherent, that would limit them to a purpose relating to prion decontamination. Any reason to have combined the elements identified in the prior art would therefore be adequate motivation. In re Dillon, 919 F.2d at 693, 16 USPQ2d at 1901 (Fed. Cir. 1990).

Claims 74, 80, 82

Claims 74, 80, and 82 stand rejected over Huth and further in view of Shih[3].

The key difference between representative claims 56 and 82 is the recitation in claim 82 of the specific keratinase "Bacillus licheniformis PWD-1 keratinase." This enzyme is disclosed in Shih, where it is described as having an optimal reaction temperature of 45-50°C. See Shih, Abstract; column 14, lines 25-27. Keratinases are

described by Huth as "suitable proteolytic enzymes" in for cleaning and disinfection. Huth, column 15, lines 13-15.

We agree with the examiner that the skilled worker would have been motivated to have utilized the particular keratinase disclosed in Shih in view of Huth's suggestion that this class of enzymes is useful for disinfection purposes and the skilled worker's reasonable expectation that it would have similar properties as being a member of the same enzyme class. See, e.g., Dillon, 919 F.2d at 693, 696, 16 USPQ2d at 1901, 1904. Appellant did not separately argue this limitation, and there was no evidence of record that one type of keratinase is any better than another.

New Grounds of Rejection

Under the provisions of 37 C.F.R. § 41.50(b), we enter the following new grounds of rejection.

Indefiniteness, 35 U.S.C. § 112, second paragraph

Claims 39-51, 53-55, 63, 71, 73, 74, and 80 are rejected under § 112, second paragraph, as being indefinite.

The independent claims are reproduced below:

> 39. A system comprising:
> (a) one or more articles susceptible to contamination by infectious prion protein;
> (b) means for heating said articles;
> (c) a proteolytic enzyme selected from the group consisting of keratinases and subtilisins; and
> (d) means for exposing said articles to said proteolytic enzyme;
> wherein said one or more articles are characterized by a first elevated temperature of at least 40°C and not more than 150°C during a first duration, wherein said articles are characterized by a second elevated

[3] Shih et al. (Shih), U.S. Pat. No. 5,171,682, issued Dec. 15, 1992.

temperature in a range of from about 50°C to about 65°C and exposure to said proteolytic enzyme during a second, subsequent duration.

71. A system comprising (a) a surgical instrument contaminated with infective prior protein; (b) means for heating the surgical instrument; (c) a proteolytic enzyme that is thermally stable at a temperature in a range of from about 35°C to about 100°C and proteolytically effective to at least partially destroy the infective prion protein contaminating said surgical instrument, and (d) means for exposing the surgical instrument to the proteolytic enzyme,
wherein said surgical instrument is characterized by a first elevated temperature in a range of from about 100°C to about 150°C during a first duration, and wherein said surgical instrument is characterized by a second elevated temperature in a range of from about 35°C to about 100°C and exposure to said proteolytic enzyme during a second, subsequent duration.

80. A system comprising:
(a) one or more articles susceptible to contamination by infectious prion protein;
(b) means for heating said articles;
(c) Bacillus lichenformis PWD-I keratinase; and
(d) means for exposing the heated articles to the Bacillus lichenformis PWD-1 keratinase,
wherein said articles are characterized by a first elevated temperature of at least 40°C and not more than about 150°C during a first duration, and wherein said articles are characterized by second elevated temperature in a range of from about 50°C to about 65°C and exposure to Bacillus lichenformis PWD-1 keratinase during a second, subsequent duration.

The meaning of the "wherein clause" in independent claims 39, 71, and 80 was a significant source of contention between the examiner and Appellant in this appeal. The examiner's position was that the recited clause is a functional limitation that describes an "intended use" of the claimed system. Answer, pages 8-9. Appellant disagreed, arguing that the clause characterizes the "physical state" of the articles in the system, and imposed "implicit structural limitations" on it. Brief, page 9; Reply Brief, paragraph spanning pages 5-6.

The "wherein clause" reciting the two-temperature requirement was not present in the application as originally filed. After a restriction that divided the claims into (1)

proteolytic enzyme composition and (2) method groups, Appellant morphed original claim 39, which was directed to a proteolytic enzyme composition, into a "system" claim for disinfecting articles susceptible to prion contamination. In addition to the presence of the enzyme, the claim was amended to include: "articles" (e.g., instruments to be sterilized); "means for heating" articles, and "means for exposing said articles to proteolytic enzymes." Amendment filed 9/23/2003. Later, in response to prior art rejections, Appellant added the "wherein clause," stating that it expressly characterized the recited articles by requiring "two distinctive physical states [temperature] at two different durations." Amendment filed 4/16/2004, page 21. Basically, Appellant was amending the composition claim to include the restricted method limitations, i.e., heating articles to a temperature that causes the prion to become susceptible to proteolytic digestion, followed by contacting with a proteolytic enzyme under suitable temperature conditions to digest the prion protein.

As we understand it, Appellant is claiming the system as it performs a disinfection process, where the articles are first held at about 40-150°C to make the prion susceptible to proteolysis, and then at about 50-65°C for digestion ("exposure") by a proteolytic enzyme. (Claim 71 recites different ranges, but the concept is the same.) This is consistent with the statement in the application that the invention includes a two-step sequence involving two temperature exposures. Specification, page 10. Although the claims recite temperature ranges, we understand this to mean that the article is brought to a temperature within the range, and that it may also pass through other temperatures within the recited range.

The problem with this construction is that claims 39, 71, and 80, by Appellant's own admission, would place the system at two different temperatures at the same time. Response filed 4/16/2004, Page 21. We don't understand how this configuration could exist. It is like claiming a milk product which is simultaneously both frozen solid and in the form of warm milk. One way out of this conflict would be to construe the claims to contain two separate articles, each "characterized by" (i.e., having the property of) one of the two different temperatures recited in the claims. Although the claims refer to "one or more articles," the antecedent basis in the "wherein clause" does not clearly express this two-article requirement. The examiner's position that the "wherein clause" is a functional limitation of the system may resolve the apparent conflict, but surely flies in the face of the plain language ("characterized by") of the claims.

The purpose of § 112, second paragraph, is to ensure that the claim scope is clear. The "wherein clause" in describing the system to be characterized by two different temperature ranges does not clearly define the scope of the claim. It is not evident how the system can be simultaneously be at a "first elevated temperature" and a "second elevated temperature" where enzyme is present. To the contrary, the specification indicates that the first and second temperatures are experienced by the system at different times. Since claims 39-51, 53-55, 63, 71, 73, 74, and 80 are "not amenable to construction" and are "insolubly ambiguous," we find these claims to be indefinite under § 112, second paragraph. Datamize, LLC v. Plumtree Software, Inc., 417 F.3d 1342, 1347, 75 USPQ2d 1801, 1804 (Fed. Cir. 2005).

Claims 39-51, 53-56, 63, 71, 73, 74, 80, and 82 are further rejected under § 112, second paragraph, as being indefinite in the recitation of the "means for" limitations.

Independent claims 39, 56, 71, 80, and 82 recite "means for heating" and "means for exposing." These are means-plus-function limitations, where the function is "heating" and "exposing," respectively.

When a claim limitation is expressed in means-plus-function language and does not recite definite structure in support of its function, the limitation is subject to 35 U.S.C. §112, ¶ 6. Braun Med., Inc. v. Abbott Labs., 124 F.3d 1419, 1424, 43 USPQ2d 1896, 1900 (Fed. Cir. 1997). "35 U.S.C. §112, ¶6, mandates that 'such a claim limitation 'be construed to cover the corresponding structure ... described in the specification and equivalents thereof.'" Id. Accordingly, when faced with means-plus-function limitations, courts "must turn to the written description of the patent to find the structure that corresponds to the means recited in the [limitations]." Id. "If one employs means plus function language in a claim, one must set forth in the specification an adequate disclosure showing what is meant by that language. If an applicant fails to set forth an adequate disclosure, the applicant has in effect failed to particularly point out and distinctly claim the invention as required by the second paragraph of section 112." In re Donaldson Co., 16 F.3d 1189, 1195, 29 USPQ2d 1845, 1850 (Fed. Cir. 1994) (in banc). See also Budde v. Harley-Davidson, Inc., 250 F.3d 1369, 1376, 58 USPQ2d 1801, 1806 (Fed. Cir. 2001); Cardiac Pacemakers, Inc. v. St. Jude Med., Inc., 296 F.3d 1106, 1115-18, 63 USPQ2d 1725, 1731-34 (Fed. Cir. 2002).

Although the claims contain means-plus-function language, no support can be found in the specification for structures which correspond to these means. Accordingly, we find the claims to be indefinite under § 112, second paragraph.

Summary

The rejection of claims 56 and 82 under § 103(a) as unpatentable is affirmed. Claims 39-51, 53-55, 63, 71, and 73 fall with claim 56; claims 74 and 80 fall with claim 82.

A new ground of rejection under § 112, second paragraph is set forth for claims 39-51, 53-56, 63, 71, 73, 74, 80, and 82.

Regarding the affirmed rejection(s), 37 CFR § 41.52(a)(1) provides "[a]ppellant may file a single request for rehearing within two months from the date of the original decision of the Board."

In addition to affirming the examiner's rejection(s) of one or more claims, this decision contains a new ground of rejection pursuant to 37 CFR § 41.50(b) (effective September 13, 2004, 69 Fed. Reg. 49960 (August 12, 2004), 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)). 37 CFR § 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review."

37 CFR § 41.50(b) also provides that the appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

> (1) Reopen prosecution. Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the proceeding will be remanded to the examiner. . . .
>
> (2) Request rehearing. Request that the proceeding be reheard under § 41.52 by the Board upon the same record. . . .

Should the appellant elect to prosecute further before the examiner pursuant to 37 CFR § 41.50(b)(1), in order to preserve the right to seek review under 35 U.S.C. §§ 141 or 145 with respect to the affirmed rejection, the effective date of the affirmance is deferred until conclusion of the prosecution before the examiner unless, as a mere incident to the limited prosecution, the affirmed rejection is overcome.

If the appellant elects prosecution before the examiner and this does not result in allowance of the application, abandonment or a second appeal, this case should be returned to the Board of Patent Appeals and Interferences for final action on the affirmed rejection, including any timely request for rehearing thereof.

AFFIRMED

Demetra J. Mills
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Eric Grimes) BOARD OF PATENT
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